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[S. 2512, Adding Zika Virus to the FDA Priority Review Voucher Program Act](#)

FLOOR SITUATION

On Tuesday, April 12, 2016, the House will consider [S. 2512](#), the Adding Zika Virus to the FDA Priority Review Voucher Program Act, under suspension of the rules. S. 2512 was introduced on February 8, 2016, by Sen. Al Franken (D-MN), and was referred to the Senate Health, Education, Labor, and Pensions Committee, which ordered the bill reported favorably, with an amendment in the nature of a substitute, on March 15, 2016. The bill was passed with an amendment by Unanimous Consent in the Senate on March 17, 2016.

SUMMARY

S. 2512 amends the Federal Food, Drug, and Cosmetic Act to add the Zika virus to the list of tropical diseases under the priority review voucher program.

BACKGROUND

The Zika virus is spread to people primarily through the bite of an infected mosquito. The most common symptoms of Zika are fever, rash, joint pain, and conjunctivitis. However, the virus can spread from a pregnant woman to her unborn child, and has been linked to serious birth defects. In May 2015, the Pan American Health Organization issued an alert regarding the first confirmed Zika virus infection in Brazil, and on February 1, 2016, the World Health Organization declared Zika virus a public health emergency of international concern.¹

The Food and Drug Administration (FDA) can award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. A voucher entitles the holder to have a future new drug or biological product application acted upon by the FDA within six months.²

COST

A Congressional Budget Office estimate is unavailable at this time.

¹ See <http://www.cdc.gov/zika/about/index.html>

² See [Rare Pediatric Disease Priority Review Voucher Program](#)

STAFF CONTACT

For questions or further information please contact [Jake Vreeburg](#) with the House Republican Policy Committee by email or at 5-0190.